Remarks

The Office Action mailed 3 December 2003 has been received and reviewed. Claims 44-53 having been cancelled, and claims 54-63 having been added, the pending claims are claims 1-43 and 54-63. Claims 22-24, 31, 32, 35, 36, 40 having been withdrawn by the Examiner in a Restriction Requirement, the claims currently under examination are claims 1-21, 25-30, 33, 34, 37-39, 41-43, and 54-63.

Reconsideration and withdrawal of the rejections are respectfully requested. Also, Applicants request rejoinder of the withdrawn claims on the basis that the independent claims are linking claims or are so related that they place no examination burden on the Examiner.

The amendments to the specification update the application serial number, filing date, and publication number in a cited application.

Support for claim 54 can be found at page 15, lines 23-26 in the specification.

Support for claims 55 and 60 can be found at page 13, lines 6-8 in the specification.

Support for claims 56 and 61 can be found at page 15, lines 7-9 in the specification.

Support for claims 57 and 62 can be found at page 12, lines 3-6 in the specification.

Support for claims 58 and 59 can be found in claims 1 and 13 as originally filed and at page 15, lines 23-26 in the specification.

Support for claim 63 can be found at page 11, line 31 through page 12, line 2.

Information Disclosure Statement

An Information Disclosure Statement was filed with the U.S. Patent and Trademark Office on 21 August 2002 in the present matter. While a copy of the Information Disclosure Statement listing the co-related applications has been initialed and returned, copies of the initialed 1449 forms have not been returned. For the Examiner's convenience, copies of the Information Disclosure Statement, 1449 forms, and return-stamped receipt postcard are attached (marked as Exhibit A) with this Amendment and Response. Applicant's Representative

respectfully request that the 1449 forms be initialed and returned with the next official communication.

Obviousness-Type Double Patenting Rejection

Claims 1-21, 25-30, 33, 34, 37-39, and 41-43 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 16-25, 27, 29-44, 47, and 48-60 of copending Application No. 10/052,158 in view of Kross (U.S. Patent No. 5,618,841), Brink et al. (U.S. Patent No. 5,173,291) and Beach (U.S. Patent No. 3,380,923). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, Second Paragraph and 35 U.S.C. §101 Rejections

The Examiner rejected claims 7-9, 28, 37, and 42 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner stated that a single claim which claims both a product and process steps of using the product is indefinite under 35 U.S.C. §112, second paragraph. Furthermore, the Examiner rejected the claims under 35 U.S.C. §101 based on the theory that the claim is directed to neither a "process" nor a "composition of matter," but rather embraces or overlaps two different statutory classes of invention. This rejection is respectfully traversed.

These claims describe the composition in terms of various characteristics. They are not directed to methods of use. For example, claims 7-9 describe the antiseptic characteristics of the composition in terms of a specific test and the desired results of that test. Again, this test language is not directed to a method of using, but rather, is it directed to a means of characterizing the composition. Accordingly, such claims do not violate either §112 of §101. Therefore, removal of these rejections is respectfully requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-21, 25-30, 33, 34, 37-39, and 41-43 under 35 U.S.C. §103(a) as being unpatentable over Kross (U.S. Patent No. 5,618,841) in view of Brink et al. (U.S. Patent No. 5,173,291) and Beach (U.S. Patent No. 3,380,923). This rejection is traversed.

Claims 1-38, 41, 42, 43, and 54-63 of the present application relate to an antiseptic composition. The antiseptic composition includes an antimicrobial agent selected from I_2, an iodophor, and a combination thereof, a hydroxycarboxylic acid buffer, water, and a substantive film-forming polymer. "Substantive" as it applies to a film-forming polymer means that when the film-forming polymer in solution is applied to human skin and dried, it resists removal under certain conditions as defined on page 6, line 32 through page 7, line 9 of the specification.

Claim 39 of the present application relates to an antiseptic composition. The antiseptic composition includes an antimicrobial agent selected from I_2, an iodophor, and a combination thereof in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%, a hydroxycarboxylic acid buffer, water, and a film-forming polymer comprising hydrophilic and hydrophobic moieties.

U.S. Patent No. 5,618,841 (Kross) discloses a composition for improving the anti-microbial activity of mammalian iodophor teat dips. The composition includes an iodophor and a specific organic acid buffer (column 2, lines 43-55). The composition may also include certain polymeric materials (column 5, lines 42-53). These polymers are not all necessarily substantive in the above-described meaning or comprise hydrophilic and hydrophobic moieties. These are significant features of the class of film-forming polymers used in Applicant's invention. Furthermore, even if there are substantive film-forming polymers or film-forming polymers that comprise hydrophilic and hydrophobic moieties within the classes of film-forming polymers disclosed in Kross, there is no teaching or suggestion in Kross that such polymers could be selected and combined with the other components in the recited amounts in Applicant's claims to form an antiseptic composition. For this reason the subject-matter of instant claims is novel in view of Kross.

Furthermore the compositions of Kross comprise a specific organic acid buffer. Although Kross mentions that, theoretically, concentrations of the organic acid buffer of from about 0.05% to 5.0% can be used, a concentration range of from 0.1% to 3.0% is given as being typical, while the preferred range is from 0.2% to 2% (column 5, lines 29-32). Moreover, the concentration of the organic buffers employed in the Examples ranges from 0.25% to 1.42% (column 6, line 15 to column 7, line 35). Since the instant claims require that the hydroxycarboxylic buffer is present in an amount of at least 5 wt-%, the only possible point of overlap is the edge value of 5 wt-%, which is mentioned as a theoretical upper limit in Kross. However, such high amounts of buffer are never used in Kross and the preferred range of Kross (from 0.2% to 2%) is far removed from this one point of possible overlap. The higher level of buffer used in the present application is particularly desirable in those iodophor-containing antiseptic compositions, in particular because the level of rapid microbial kill increases significantly with the concentrations of the hydroxycarboxylic acid (present application, page 13, lines 23-27).

Applicants have found that the presently claimed compositions comprising a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-% (and particularly in excess of 5 wt-%) in combination with the substantive film forming polymers are substantially nonirritating to tissue. This finding is particularly surprising in view of the fact that previous reports had indicated that high levels of alpha-hydroxy acids at an acidic pH can be irritating to the skin (present application, page 13, lines 9-22). See, for example, U.S. Patent Nos. 6,521,222 (column 1, lines 34-42 and column 2, lines 11-15), 6,277,881 (column 1, lines 12-21), and 5,958,436 (column 2, lines 39-68), for additional support for this statement regarding previous reports.

Moreover, high concentrations of hydroxycarboxylic acid buffers would be expected to contribute to poor PSA-coated product adhesion and significantly reduced substantivity, since hydrophilic compounds facilitate moisture build-up from transpiration and perspiration in combination with external fluid exposure, resulting in premature adhesion failure (present application, page 15, lines 16-26). Surprisingly, Applicants found that, with certain

hydroxycarboxylic acid buffers, concentrations of at least about 5 wt-% (and particularly in excess of 5 wt-%) in combination with the substantive film forming polymers still allow sufficient PSA-coated product adhesion and good substantivity. Hence, the combination claimed in the present application provides surprising advantages.

Furthermore, with respect to claim 29, for example, the Examiner indicates that Kross discloses surfactants. Although the Examples all refer to IGEPAL CO-720, which is nonylphenol ethoxylate with 12 moles of ethylene oxide (also referred to as nonylphenoxy polyoxy-ethanol, N=12), this polyether glycol forms an iodophor with iodine (see column 3, lines 28-32). There is no teaching or suggestion of a separate surfactant in the compositions of Kross.

U.S. Patent No. 5,173,291 (Brink et al.) does not provide that which is missing from Kross. It discloses the use of citric acid in a buffer solution in Examples 27-48. Examples 45 and 47-48 disclose the use of 5 grams of the buffer solution. The buffer solution is described at column 13, lines 27-32 (29.25 mLs of a 0.1M citric acid monohydrate solution and 70.75 mLs of a 0.20M disodium phosphate solution). This equates to a very small amount (less than 0.1 wt-%) of a hydroxycarboxylic acid. There is no teaching or suggestion of a composition with the high amount of hydroxycarboxylic acid buffer, as recited in Applicants' claims.

U.S. Patent No. 3,380,923 (Beach) does not provide that which is missing from Kross or Brink et al. In fact, there is no teaching or suggestion of compositions that include hydroxycarboxylic acids in Beach. Thus, there is no motivation to combine this document with either of the others.

It is respectfully submitted that there is no teaching or suggestion in the prior art of how to provide antiseptics having increased speed of bactericidal activity on skin without substantial irritation while still allowing adhesion of PSA-coated products and good substantivity. There is no indication to be found in the combination of Kross, Brink et al., and Beach that this problem can be solved by providing one of the antiseptic compositions of the present invention that contain, among other components, a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-% (and particularly in excess of 5 wt-%).

For the reasons presented above, the subject-matter of the present claims is not obvious in view of the cited documents, considered alone or together in any combination.

Summary

It is respectfully submitted that the pending claims 1-43 and 54-63 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3rd. day of March, 2004, at 1:57 p.m. (Central Time).

By: Rachel Gagliardi - Graham
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